AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

HYDROGEN PEROXIDE (35% PEROX-AID®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS

DEVELOPED UNDER THE FEDERAL-STATE AQUACULTURE DRUG APPROVAL PARTNERSHIP PROJECT, A PROJECT OF THE ASSOCIATION OF FISH AND WILDLIFE AGENCIES

Rosalie A. Schnick
National Coordinator for Aquaculture New Animal Drug Applications
Michigan State University
3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088
Phone (608) 781-2205; Fax (608) 783-3507
E-mail: RozSchnick@centurytel.net

Website: http://aquanic.org/aquadrugs

HYDROGEN PEROXIDE (35% PEROX-AID®)
(Version 2, March 2008)

ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AADAP	Aquatic Animal Drug Approval Partnership Program—Dr. David Erdahl, U.S. Fish and Wildlife Service, 4050 Bridger Canyon Road, Bozeman, Montana 59715; Phone: 406-994-9904; Fax: 406-582-0242; E-mail: Dave_Erdahl@fws.gov
AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CVM	Aquaculture Drugs Team (HFV-131), Division of Therapeutic Drugs for Food Animals, Office of New Animal Drug Evaluations, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855; Dr. Donald Prater; Phone: 240-276-8343; E-mail: Donald.Prater@fda.hhs.gov
Efficacy	Effectiveness Technical Section includes pivotal & supportive studies that show whether or not a drug is effective for its intended use [21 CFR § 514.1(b)(8)(i)]
EKA	Sponsor of hydrogen peroxide (35% PEROX-AID®): Dr. David Lovetro, Eka Chemicals Inc., 1519 Johnson Ferry Road, Marietta, Georgia 30062; Phone: 770-321-4198; Fax: 770-578-1359; E-mail: DLovetro@EkaChem.com
FOI	Final Freedom of Information summary generated by CVM based on draft FOIs developed by researchers for each study [21 CFR § 514.11(e)(2)(ii)]
INAD	Investigational New Animal Drug exemption [21 CFR 511]
Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR § 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: RozSchnick@centurytel.net
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR § 514.1(b)(4-6)]
PMF	Public Master File can contain safety and efficacy data and information generated with public funds (Guidance Document #57)
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, subchronic) (Guidance Document #3)
UMESC	Upper Midwest Environmental Sciences Center—Mark Gaikowski, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: MGaikowski@usgs.gov

KEY TO COLOR CODING

COLOR	STATUS
	No current plans and/or funds
	In progress or planned; funded
	Submitted to CVM
	Accepted as complete by CVM

HYDROGEN PEROXIDE (35% PEROX-AID®)

Hydrogen peroxide (35% PEROX-AID®) NADA approvals (1/11/07)

Indications:
For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare (Flexibacter columnaris)*

Dosages:

Freshwater-reared finfish eggs: 500 to 1000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs or 750 to 1000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all warmwater species of freshwater-reared finfish eggs.

Freshwater-reared finfish:

Freshwater-reared salmonids: 100 mg/L for 30 minutes or 50 to 100 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

Coolwater species of freshwater-reared finfish (except northern pike & paddlefish) and channel catfish*: 50 to 75 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

Coolwater species of freshwater-reared finfish fry (except northern pike, pallid sturgeon & paddlefish) and channel catfish fry*: 50 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath.

*Initial bioassay on a small number is recommended before treating the entire group
Use with caution on walleye.

HYDROGEN PEROXIDE (35% PEROX-AID®)

Status of Technical Sections that support all supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	EKA (INAD #9671)—Product chemistry package for 35% PEROX-AID®—accepted 2/11/04	None
Environmental Safety (continuous flow-through systems)	UMESC (INAD #10-023)—Environmental Safety/Environmental assessment/continuous flow-through systems/final revision incorporating 21-day chronic *Daphnia* study—accepted 6/22/06	None
Human Food Safety (toxicology)	EKA (INAD #9671)—Human Food Safety/toxicology—accepted 3/22/00	None
Human Food Safety (residue chemistry/all finfish)	EKA (INAD #9671)—Human Food Safety/residue chemistry—accepted 3/22/00 (no tolerances, withdrawal times, Acceptable Daily Intake limits, or regulatory methods required)	None
Human Food Safety (microbiological effects on bacteria of human health concern/all finfish)	EKA (INAD #9671) & NADA Coordinator—Human Food Safety/Guidance Document #152: microbiological effects on bacteria of human health concern/all finfish —accepted 6/6/05	None
Human Food Safety (safety of residues in human food/all finfish)	EKA (INAD #9671) & NADA Coordinator—Human Food Safety/ Guidance Document #159: safety of residues in human food/all finfish)—accepted 9/16/05	None
Target Animal Safety (all finfish)	UMESC (INAD #10-023 & PMF #5639)—Target Animal Safety/all finfish—accepted 10/4/01	None
Target Animal Safety (all finfish eggs)	UMESC (INAD #10-023 & PMF #5639)—Target Animal Safety/all finfish eggs—accepted 11/26/03	None

HYDROGEN PEROXIDE (35% PEROX-AID®)

LABEL CLAIM #1:
SPECIES: FRESHWATER-REARED FINFISH
INDICATIONS: **For the control of mortality in freshwater-reared finfish due to saprolegniasis**
DIRECTIONS FOR USE: Apply 35% PEROX-AID® at a concentration of 50 to 100 milligrams hydrogen peroxide per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath for 60 minutes or 100 mg/L in continuous flow water supply of freshwater-reared salmonid, largemouth bass, and muskellunge culture units or as a static bath for 30 minutes once per day on alternate days in a tiered dosing system as follows:

Species	Dose	Duration
Freshwater-reared salmonids, largemouth bass, and muskellunge	50-100 mg/L	60 minutes
	100 mg/L	30 minutes
All freshwater-reared finfish fingerlings and adults[1,3]	50-75 mg/L	60 minutes
All freshwater-reared finfish fry [1,2,3]	50 mg/L	60 minutes

1. Except northern pike or paddlefish
2. Except northern pike or pallid sturgeon
3. An initial bioassay on a small number is recommended before treating the entire group.

Use caution on walleye *Sander vitreus*

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (Saprolegniasis/ channel catfish)	**UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy/studies/Saprolegniasis/channel catfish—accepted 11/24/04**	**Needed—To complete this Technical Section, need supporting efficacy data on channel catfish for a channel catfish label claim**
Efficacy (Saprolegniasis/ freshwater-reared finfish other than catfish)	**No entities identified—Efficacy studies/Saprolegniasis/freshwater-reared finfish—not planned**	**Needs to be planned**
Label	**EKA (INAD #9671) & NADA Coordinator—Label—planned if efficacy accepted**	**None—pending acceptance**
FOI	**CVM—FOI—planned if efficacy accepted**	**None—pending acceptance**
AOI	**EKA (INAD #9671) & NADA Coordinator—AOI—planned if efficacy accepted**	**None—pending acceptance**
NADA Package	**EKA (INAD #9671) & NADA Coordinator—35% PEROX-AID® NADA package—planned if efficacy accepted**	**None—pending acceptance**

HYDROGEN PEROXIDE (35% PEROX-AID®)

LABEL CLAIM #2:
SPECIES: FRESHWATER-REARED FINFISH EXCEPT COOLWATER FISH AND CHANNEL CATFISH
INDICATIONS: **For the control of mortality in freshwater-reared finfish except coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)**
DIRECTIONS FOR USE: Apply 35% PEROX-AID® at a concentration of 50 to 75 milligrams hydrogen peroxide per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in finfish culture units for 60 minutes once per day on alternate days for three treatments in a tiered dosing system as follows:

Species	Dose	Duration
Freshwater-reared salmonids, largemouth bass, and muskellunge	50-100 mg/L	60 minutes
	100 mg/L	30 minutes
All freshwater-reared finfish fingerlings and adults[1,3]	50-75 mg/L	60 minutes
All freshwater-reared finfish fry [1,2,3]	50 mg/L	60 minutes

1. Except northern pike or paddlefish
2. Except northern pike or pallid sturgeon
3. An initial bioassay on a small number is recommended before treating the entire group.

Use caution on walleye *Sander vitreus*

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (columnaris disease/all coolwater fish & channel catfish)	**UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy studies/external columnaris disease/all coolwater fish & channel catfish—accepted 11/21/03 and label claim approved 1/11/07**	**None**
Efficacy (columnaris disease/freshwater-reared finfish other than coolwater finfish & channel catfish)	**EKA (INAD #9671), AADAP (INAD #11-669), & UMESC (INAD #10-023 & PMF #5639)—Efficacy studies/columnaris disease/freshwater-reared finfish other than coolwater finfish & channel catfish—being planned or in progress**	**None—pending acceptance**
Label	**EKA (INAD #9671) & NADA Coordinator—Label—planned if efficacy accepted**	**None—pending acceptance**
FOI	**CVM—FOI—planned if efficacy accepted**	**None—pending acceptance**
AOI	**EKA (INAD #9671) & NADA Coordinator—AOI—planned if efficacy accepted**	**None—pending acceptance**
NADA Package	**EKA (INAD #9671) & NADA Coordinator—35% PEROX-AID® NADA package—planned if efficacy accepted**	**None—pending acceptance**

HYDROGEN PEROXIDE (35% PEROX-AID®)

LABEL CLAIM #3:
SPECIES: COOLWATER AND WARWATER FINFISH
INDICATIONS: For the control of mortality in coolwater and warmwater finfish due to bacterial gill disease associated with *Flavobacterium branchiophilum*.
DIRECTIONS FOR USE: Apply 35% PEROX-AID® at a concentration of 50 to 75 milligrams hydrogen peroxide per liter of culture water [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply or as a static bath in finfish culture units for 60 minutes once per day on alternate days for three treatments in a tiered dosing system as follows:

Species	Dose	Duration
Freshwater-reared salmonids, largemouth bass, and muskellunge	50-100 mg/L	60 minutes
	100 mg/L	30 minutes
All freshwater-reared finfish fingerlings and adults[1,3]	50-75 mg/L	60 minutes
All freshwater-reared finfish fry [1,2,3]	50 mg/L	60 minutes

1. Except northern pike or paddlefish
2. Except northern pike or pallid sturgeon
3. An initial bioassay on a small number is recommended before treating the entire group.

Use caution on walleye *Sander vitreus*

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/freshwater-reared salmonids)	**UMESC (INAD #10-023 & PMF #5639)—Pivotal efficacy studies/bacterial gill disease/all freshwater-reared salmonids—accepted 10/12/00 and label claim approved 1/11/07**	**None**
Efficacy (bacterial gill disease/coolwater & warmwater finfish)	**EKA (INAD #9671), AADAP (INAD #11-669), & UMESC (INAD #10-023 & PMF #5639)—Efficacy studies/ bacterial gill disease/coolwater & warmwater finfish—being planned or in progress**	**None—pending acceptance**
Label	**EKA (INAD #9671) & NADA Coordinator—Label—planned if efficacy accepted**	**None—pending acceptance**
FOI	**CVM—FOI—planned if efficacy accepted**	**None—pending acceptance**
AOI	**EKA (INAD #9671) & NADA Coordinator—AOI—planned if efficacy accepted**	**None—pending acceptance**
NADA Package	**EKA (INAD #9671) & NADA Coordinator—35% PEROX-AID® NADA package—planned if efficacy accepted**	**None—pending acceptance**

LABEL CLAIM #4:
SPECIES: FRESHWATER-REARED FINFISH
INDICATIONS: **For the control of external protozoa and monogenetic trematodes in freshwater-reared finfish**
DIRECTIONS FOR USE: Apply 35% PEROX-AID® at a concentration of 50 to 100 milligrams hydrogen peroxide per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath for 60 minutes or 100 mg/L in continuous flow water supply of freshwater-reared salmonid, largemouth bass, and muskellunge culture units or as a static bath for 30 minutes once per day on alternate days in a tiered dosing system as follows:

Species	Dose	Duration
Freshwater-reared salmonids, largemouth bass, and muskellunge	50-100 mg/L	60 minutes
	100 mg/L	30 minutes
All freshwater-reared finfish fingerlings and adults[1,3]	50-75 mg/L	60 minutes
All freshwater-reared finfish fry [1,2,3]	50 mg/L	60 minutes

1. Except northern pike or paddlefish
2. Except northern pike or pallid sturgeon
3. An initial bioassay on a small number is recommended before treating the entire group.

Use caution on walleye *Sander vitreus*

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external protozoa & monogenetic trematodes/all salmonids)	**UMESC (INAD #10-023 & PMF #5639)—Efficacy studies/external protozoa & monogenetic trematodes/rainbow trout—accepted as supportive 9/26/02**	**Needed—To complete this Technical Section, need pivotal efficacy data on salmonids**
Efficacy (external protozoa & monogenetic trematodes/freshwater-reared salmonids)	**EKA (INAD #9671) and other entities—Pivotal efficacy/studies/external protozoa & monogenetic trematodes/freshwater-reared salmonids—being planned**	**None—pending acceptance**
Efficacy (external protozoa & monogenetic trematodes/freshwater-reared finfish other than salmonids)	**EKA (INAD #9671) and other entities—Supportive efficacy/studies/external protozoa & monogenetic trematodes/freshwater-reared finfish other than salmonids—being planned**	**None—pending acceptance**
Label	**EKA (INAD #9671) & NADA Coordinator—Label—planned if efficacy accepted**	**None—pending acceptance**
FOI	**CVM—FOI—planned if efficacy accepted**	**None—pending acceptance**
AOI	**EKA (INAD #9671) & NADA Coordinator—AOI—planned if efficacy accepted**	**None—pending acceptance**
NADA Package	**EKA (INAD #9671) & NADA Coordinator—35% PEROX-AID® NADA package—planned if efficacy accepted**	**None—pending acceptance**

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LABEL CLAIM #5:
SPECIES: ***SERIOLA RIVOLIANA***
INDICATIONS: **For the control of *Neobenedenia* spp. in *Seriola rivoliana***
DIRECTIONS FOR USE: Apply 35% PEROX-AID® at a concentration of 50 to 100 milligrams hydrogen peroxide per liter [mg/L; equivalent to parts per million (ppm)] as a static bath for 60 minutes or 100 mg/L as a static bath for 30 minutes once per day on alternate days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Environmental Safety (saltwater systems)	**No known entities—Environmental Safety/environmental assessment revision/saltwater systems—not planned but funding being sought**	**Needs to be planned & funded**
Target Animal Safety (*Seriola rivoliana*)	**No known entities—Target animal safety/*Seriola rivoliana*—not planned but funding being sought**	**Needs to be planned & funded**
Efficacy (*Neobenedenia* spp./*Seriola rivoliana*)	**No known entities—Efficacy/*Neobenedenia* spp./*Seriola rivoliana*—not planned but funding being sought**	**Needs to be planned & funded**
Label	**EKA (INAD #9671) & NADA Coordinator—Label—planned if revised EA, target animal safety, and efficacy accepted**	**None—pending acceptance**
FOI	**CVM—FOI—planned if revised EA, target animal safety, and efficacy accepted**	**None—pending acceptance**
AOI	**EKA (INAD #9671) & NADA Coordinator—AOI—planned if revised EA, target animal safety, and efficacy accepted**	**None—pending acceptance**
NADA Package	**EKA (INAD #9671) & NADA Coordinator—35% PEROX-AID® NADA package—planned if revised EA, target animal safety, and efficacy accepted**	**None—pending acceptance**